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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,976	06/20/2003	Jean-Pierre Sommadossi	06171.IDX 1007 CON3	2062

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EXAMINER	
OWENS JR, HOWARD V	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,976	SOMMADOSSI ET AL.	
	Examiner	Art Unit	
	Howard V Owens	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *89 and 130-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *131,133,134,136,138, 140 and 141* is/are allowed.

6)☐ Claim(s) *89,130,132,135,137 and 139-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 89, 130, 132, 135, 137, 139, 142, 144 – 153 are rejected under 35 U.S.C. § 102(b) as being anticipated by Koszalka et al., WO 9401117.

Claims 89, 130, 132, 135, 137, 139, 150 are drawn to a method for treating hepatitis C via administration of a nucleoside or nucleotide compound of Formula XVII or XI.

Dependent claims 142 - 146 are drawn to including anti-hepatitis C agents with the compound of Formula XVII for the treatment of hepatitis C.

Dependent claims 147 – 149 are drawn to the dosage form as a capsule or tablet containing 50 – 1000 mg.

Dependent claims 151 – 153 are drawn to a substantially pure form of the compound wherein the weight is at least 90% or 95% of the composition.

Koszalka et al. anticipates the claims as it teaches a 2' deoxy, 3' hydroxy nucleoside compound and pharmaceutically acceptable salts thereof for the treatment of hepatitis C wherein the base is an imidazolopyridine and the elemental atom present in the furanose is sulfur. Koszalka also teaches the dosage of 50 – 1000 mg in the form of a tablet or capsule (pp. 11-18) and the purity is at least 90% or 95% (see p. 23).

Koszalka also teaches the use of additional agents in the treatment such as ribavirin, nucleotide analogs (polymerase inhibitors) and interferon(p.10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 89, 130, 132, 135, 137, 139 and 142 - 153 are rejected under 35 U.S.C. § 103 as being unpatentable over Koszalka et al., WO 9401117.

Claims 89, 130, 132, 135, 137, 139 are drawn to a method for treating hepatitis C via administration of a nucleoside or nucleotide compound of Formula XVII or XI.

Dependent claims 142 – 146 are drawn to administration of a second anti-hepatitis C viral agent in combination with the compound of Formula XVII.

Dependent claims 147 – 153 are drawn to administration of the compound in a dosage unit, in tablet or capsule form wherein the compound is at least 90% or 95% by weight of the β-D-isomer.

Koszalka et al. teaches a 2' deoxy, 3' hydroxy nucleoside compound and pharmaceutically acceptable salts and esters thereof for the treatment of hepatitis C wherein the base is an imidazolopyridine and the elemental atom present in the furanose is sulfur. Koszalka also teaches the use of additional agents in the treatment such as ribavirin, interferon and polymerase inhibitors (nucleotide analogs) (p.10). Koszalka also teaches the dosage of 50 – 1000 mg in the form of a tablet or capsule (pp. 11-18) and the purity is at least 90% or 95% (see p. 23).

Koszalka does not teach helicase inhibitors as an additional agent, however, the combination of two agents known in the art to have utility separately for the same disease is obvious.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to include a helicase inhibitor as an additional agent in the treatment of hepatitis C.

A person of ordinary skill in the art would have been motivated to combine the compound of Formula XVII and a helicase inhibitor for the treatment of hepatitis C since the prior art has recognized the separate utility of these compounds to treat hepatitis C and the suggestion by the prior art to include additional anti-hepatitis C agents with the nucleoside compound for the treatment of hepatitis C.

Allowable Subject Matter

The use of the 2' fluorinated compounds set forth in dependent claims 131,133,134,136,138 and 141 to treat hepatitis C appears to be allowable over the prior art of record.

Howard V. Owens
Patent Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.